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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/679,569 10/06/2003		Carlos E. Collazo	OSTEONICS 3.0-456	3144		
530	7590 03/10/2005		EXAMINER			
LERNER, D	AVID, LITTENBERG,	REIMERS, ANNETTE R				
KRUMHOLZ	& MENTLIK			· · ·		
600 SOUTH A	AVENUE WEST	ART UNIT	PAPER NUMBER			
WESTFIELD	, NJ 07090	3732				
			DATE MAIL ED: 02/10/2005			

Please find below and/or attached an Office communication concerning this application or proceeding.

			A No.	<sub>1</sub>	A == 1!= == 4/= \			
			Application No.		Applicant(s)			
Office Action Summer		10/679,569		COLLAZO, CARLOS E.				
On	ice Action Summary		Examiner		Art Unit			
			Annette R. Reimers	*	3732			
The M Period for Reply	IAILING DATE of this commu I	nication appe	ears on the cover si	eet with the c	orrespondence ad	dress		
THE MAILING - Extensions of tin after SIX (6) MC - If the period for - If NO period for - Failure to reply Any reply receive	ED STATUTORY PERIOD R G DATE OF THIS COMMUN me may be available under the provision DNTHS from the mailing date of this com reply specified above is less than thirty ( reply is specified above, the maximum s within the set or extended period for repl red by the Office later than three months arm adjustment. See 37 CFR 1.704(b).	NICATION. s of 37 CFR 1.136 munication. (30) days, a reply of statutory period will by will, by statute, of	6(a). In no event, however within the statutory minimu Il apply and will expire SIX cause the application to be	may a reply be time of thirty (30) days (6) MONTHS from to come ABANDONE	nely filed s will be considered timel the mailing date of this or D (35 U.S.C. § 133).			
Status			•					
1)∏ Respoi	nsive to communication(s) fil	ed on						
	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.							
• —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of C	laims							
4a) Of t 5) ☐ Claim(s 6) ☑ Claim(s 7) ☐ Claim(s	<ul> <li>Claim(s) 1-24 is/are pending in the application.</li> <li>4a) Of the above claim(s) 1-11,17 and 19 is/are withdrawn from consideration.</li> <li>Claim(s) is/are allowed.</li> <li>Claim(s) 12-16,18 and 20-24 is/are rejected.</li> <li>Claim(s) is/are objected to.</li> <li>Claim(s) are subject to restriction and/or election requirement.</li> </ul>							
Application Pap	ers							
10)⊠ The dra Applica Replace	ecification is objected to by the wing(s) filed on <u>06 October</u> on the may not request that any objected to the declaration is objected to the control of th	2003 is/are: ection to the d ig the correction	a) accepted or larawing(s) be held in on is required if the d	abeyance. See rawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 Cl	FR 1.121(d).		
Priority under 3	5 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
Attachment(s)	rences Cited (PTO-892)		<b>47 □ 1-1</b> .	erview Summary	(PTO.À13)			
<ul><li>2) Notice of Draft</li><li>3) Information Dis</li></ul>	rences Cited (P10-892) sperson's Patent Drawing Review ( sclosure Statement(s) (PTO-1449 o ail Date <u>10/06/03</u> .		5)	per No(s)/Mail Da		D-152)		

Art Unit: 3732

#### **DETAILED ACTION**

#### Election/Restrictions

Applicant's election of Group III, claims 12-16 and 18 and Species III, Figures 1-5, in the reply filed on 01/03/05 is acknowledged. It is further acknowledged that applicant believes that claims 1-5 read on the elected Species. In addition, the examiner agrees with the applicant. Furthermore, claim 12 appears to be generic.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-11, 17, and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was interpreted as made **without** traverse in the reply filed on 01/03/05.

#### Specification

The specification is objected to because reference number 36, lines 19 and 26 of page 6, has inconsistent terminology, i.e. bearing surface and undersurface, respectively. Please clarify whether reference number 36 refers to bearing surface or undersurface. In addition, reference number 45, lines 8 and 11 of page 7, has inconsistent terminology, i.e. fins and flutes, respectively. Please clarify whether reference number 45 refers to fins or flutes.

### Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 12-16, 18 and 20-24 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 12, line 1, applicant positively recites part of a human, i.e. "mounted in a fixture aligned with a bone canal". Thus claims 12-16, 18 and 20-24 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

#### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which the applicant regards as the invention.

In claim 13, line 2, "said bushing central opening" lacks proper antecedent basis.

Also, in claim 13, lines 2-3, "the largest radial extent" lacks proper antecedent basis.

In claim 14, line 2, "the number of flutes" lacks proper antecedent basis.

Application/Control Number: 10/679,569

Art Unit: 3732

In claim 15, line 2, "said central opening" lacks proper antecedent basis.

In claim 16, line 2, "said central shaft" lacks proper antecedent basis.

In claim 24, line 2, "said central opening" lacks proper antecedent basis.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12-16, 18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cenis (U.S. Patent Number 3,981,604).

Cenis discloses a cylindrical bushing, e.g. figure 2, comprising a body with a bearing surface, e.g. 21 of figures 2 and 3, extending circumferentially around an outer cylindrical surface of the bushing, a longitudinal bore formed in the body (see figure 2) and a plurality of recesses extending radially outward from the bushing central bore, e.g. 22 of figure 2. In addition, the cylindrical outer bearing surface extends about an axis, which is coaxial with an axis of the longitudinal bore (see figures 2 and 3).

Each recess is capable of receiving at least two flutes (see figures 2, 4, and 5). Furthermore, the recesses are capable of extending a distance greater than the largest radial extent of the flutes of the at least two reamers, since the Cenis bushing device

can accommodate any reamer design having straight flutes (see figures 2, 4 and 5). Moreover, the bushing is capable of having a number of recesses equal to or greater than the number of flutes of each of the reamers (see figures 2, 4, and 5). In addition, the recesses and the flutes expand in width on moving radially outward from the central opening or shaft, respectively (see figure 4).

Claims 12-14, 18 and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Ball et al. (U.S. Patent Publication 2003/0163151).

Ball et al. disclose a cylindrical bushing, e.g. figure 4, comprising a body with a bearing surface, e.g. 23 of figure 4, extending circumferentially around an outer cylindrical surface of the bushing, a longitudinal bore formed in the body (see figure 4) and a plurality of recesses extending radially outward from the bushing central bore, (see figure 4). In addition, the cylindrical outer bearing surface extends about an axis, which is coaxial with an axis of the longitudinal bore (see figures 4 and 5).

Each recess is capable of receiving at least two flutes (see figure 4). Furthermore, the recesses are capable of extending a distance greater than the largest radial extent of the flutes of the at least two reamers, since the Ball bushing device can accommodate any reamer design having straight flutes (see figure 4). Moreover, the bushing is capable of having a number of recesses equal to or greater than the number of flutes of each of the reamers (see figure 4).

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cenis (U.S. Patent Number 3,981,604).

Cenis discloses the claimed invention except for where the plurality of recesses have radial ends opposite ends thereof open to the bore at a shorter radial distance from the axis of the longitudinal bore than the outer cylindrical surface of the bushing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Cenis where the plurality of recesses have radial ends opposite ends thereof open to the bore at a shorter radial distance from the axis of the longitudinal bore than the outer cylindrical surface of the bushing, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday, 9:00AM-6:30PM.

Application/Control Number: 10/679,569 Page 7

Art Unit: 3732

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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EDUARDO C. ROBERT PRIMARY EXAMINER